

**REMARKS**

Responsive to the Office Action mailed February 25, 2004, and with an extension of time of THREE MONTHS, the present paper is timely filed on or before August 25, 2004. By the present Amendment, no claims are cancelled, claim 2 is amended, and new claims 95 - 98 are presented. Accordingly, claims 1, 2, and 95 - 98 are in the application. Entry of the amendments and reconsideration of the Application are respectfully requested.

**The Claim Amendments**

Claim 2 is amended to correct an obvious grammatical error.

**The New Claims**

New claims 95 - 98 are product by process claims drawn to a novel product, crystalline venlafaxine base that is a white solid, as made by Applicants' novel crystallization process. Support for the new claims can be found in the specification at, for example, page 6, ll. 9 to 26. Applicants respectfully submit that neither the product nor the process of claims 95 - 98 are taught or suggested in the prior art of record. Applicants further respectfully submit that the new claims do not introduce new matter into the Application.

**Claim Rejections Under 35 U.S.C. § 103**

Claims 1 and 2 were rejected under 35 U.S.C. § 103 as allegedly obvious in view of Jerussi et al. WO 00/032555 (WO '555). Because WO '555 does not suggest venlafaxine base that is a white crystalline solid, Applicants respectfully traverse.

The rejection, as Applicants best understand it, starts from the proposition, *sub silencio*, that the patentability of Applicants' novel product resides in the purity of the product. Applicants respectfully submit that the patentability of their inventive product does not rest on the heretofore unachieved purity alone. Rather, Applicants were the first to possess venlafaxine base as a white crystalline solid and a novel crystallization method for making it.

In example 3 thereof, United States Patent 4,611,078 (the '078 patent) describes venlafaxine base as an oil. At page 23, line 24, WO '555 discloses that venlafaxine base is obtained as a yellow gum that gradually transforms to a yellow solid. Neither the '078 patent nor WO '555 teach venlafaxine base as a white crystalline solid.

Moreover, neither the '078 patent nor WO '555 provide any motivation to attempt to obtain venlafaxine base as a white crystalline solid with any probability of success.

Applicants respectfully submit that it is intuitively obvious to skilled artisan and routiner alike that oils and gums are more difficult to manipulate in practice. Aware of the teachings of the '078 patent and WO '555, the skilled artisan wishing to experiment with venlafaxine base (for example to convert it to pharmaceutically acceptable salts) would be dissuaded from even attempting to isolate venlafaxine base by the teachings of the prior art of record because they would expect to obtain a difficult to handle oil or gum.

Accordingly, Applicants respectfully submit that white crystalline venlafaxine base is both novel and nonobvious in view of the prior art of record. Accordingly, Applicants respectfully submit that the rejection should be withdrawn.

### **CONCLUSION**

Applicants respectfully submit that, on the basis of the foregoing amendments and remarks, the claims are in condition for allowance, which allowance is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would advance the prosecution of the Application, the Examiner is invited to telephone the undersigned attorney.

### **REQUEST FOR EXTENSION OF TIME**

Applicants respectfully request a three-month extension of time in which to respond to the Office Action mailed February 25, 2004. The three-month extended period expires on August 25, 2004.

The Office is authorized to charge the **\$950.00** extension fee and any additional fees to the deposit account of **Kenyon & Kenyon**, Deposit Account Number **11-0600**.

### **AUTHORIZATION TO DEBIT DEPOSIT ACCOUNT**

The Office is further authorized to charge any additional fees required in relation to this paper, or credit any over payments under 37 C.F.R. \*1.16 or \* 1.17 to Deposit Account No. **11-0600**, referencing Attorney Docket No. **01662/54902**.

Respectfully submitted,

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